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In re application of Ernest Arenas et al. :
Serial No. : 09/980,913 : DECISION ON PETITION
Filed : May 31, 20002 :
Attorney Docket No.: 0380-PO2709US0 :

This is in response to applicants' petition, filed January 6, 2004 under 37 CFR 1.144, to withdraw the restriction requirement set forth by the examiner.

BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 371 as the National Stage of PCT/EP00/03842, filed May 31, 2002, which claims priority to U.S. provisional application 60/139,111, filed June 14, 1999. The application, as filed with preliminary amendments, contained claims 1-15, 19-21, 23-43, 48-54 and 58. In a first Office action mailed March 19, 2003, the examiner set forth a restriction / lack of unity requirement under 35 U.S.C. 121 and 372 dividing the claims into 7 groups as follows:

Group I, claims 1-12, 19-21, 32-40 drawn to methods of inducing a dopaminergic neuronal fate for a neural stem cell or neural progenitor cell, comprising expressing Nurr1 above basal levels in the neural stem cell or neural progenitor cell, and the dopaminergic neuronal cell produced thereby; as well as methods drawn to screening for a factor or factors that induce a dopaminergic fate in a neural stem or progenitor cell expressing Nurr1 above basal levels.

Group II, claims 13-15, 41-43 drawn to a process of producing a medicament comprising a dopaminergic neuron and use of the medicament for transplantation into the brain of a subject.

Group III, claims 23-24, 58 drawn to use of a dopaminergic neuron in methods of screening for an agent for use in treatment of a neurodegenerative disease, as well as drawn to a method directed towards using a dopaminergic neuron in methods of screening for compounds that enhance an ability of the neuron to recover from or tolerate a toxic compound.

Group IV, claims 25-28, drawn to a method of formulating into a composition an agent that improves the ability of a dopaminergic receptor to recover from or tolerate a toxin and administration of the composition comprising the agent to an individual.

Group V, claims 29-31, drawn to a method of screening for a receptor or receptors for factors obtained from Type I astrocytes, comprising comparing neural stem and progenitor cells with or without expression of Nurr-1 to identify the receptors).

Group VI, claims 48-51, drawn to methods of screening for a substance which modulates the ability of Type I astrocytes, or molecules obtained from such astrocytes, to induce a dopaminergic fate in neural stem or progenitor cells.

Group VII, claims 52-54, drawn toward administration to an individual of a composition that modulates the ability of a Type I astrocyte, or molecules produced therefrom, to induce a dopaminergic fate in a neuronal stem or progenitor cell.

In a response filed April 28, 2003 applicants elected Group I, with traverse. On July 16, 2003 the examiner mailed a first Office action on the merits, in which the restriction requirement was made final. On January 20, 2004 applicants submitted a response including an amendment which added claims 59-61.

DISCUSSION

Applicants argue that lack of unity was not found by the international search and examination authority (European Patent Office). This argument is not persuasive. The USPTO is not obligated to follow the same path as the EPO. Moreover, many claims were neither searched nor examined by the EPO for other reasons.

Applicants argue that the examiner did not correctly apply the standards for unity of invention. This is correct. However, the undersigned does not share applicants' view that no restriction requirement at all should have been made. Restriction in applications filed under 35 U.S.C. 371 is governed by 37 CFR 1.475, which states in part:

> (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
> (1) A product and a process specially adapted for the manufacture of said product; or
> (2) A product and a process of use of said product; or
> (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
> (4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.
(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.
(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

Following this guidance, a proper restriction requirement would have been as follows:

Group I: Claims 1-15 and 19-21, drawn to a method of making a product, the product made, and the first claimed method of using the product.

Group II: Claims 23-28 and 58, drawn to a second method of using the product.

Group III: Claims 29-31 and 37-43, drawn to a third method of using the product.

Group IV: Claims 32, 33 and 36, drawn to a fourth method of using the product.

Group V: Claims 34 and 35, drawn to a fifth method of using the product.

Group VI: Claims 48-54, drawn to a sixth method of using the product.

It is noted that the product itself, dopaminergic neurons, is not novel. Transplantation of dopaminergic neurons for treatment of Parkinson's disease was also known. Therefore the special technical feature of Group I is the method for making the product. This method is not included in Groups III – VI. Group II is a screening method which clearly raises different issues of patentability than the treatment method of Group I.

DECISION

Applicants' petition is **GRANTED IN PART**.

The application will be forwarded to the examiner for consideration of the response filed January 20, 2004. All claims drawn to inventions which were previously examined will be considered (i.e. claims 1-15, 19-21, 29-43 and 59-61). Claims 23-28, 48-54 and 58 will remain withdrawn from consideration.

Any request for reconsideration or review of this decision must be made by a renewed petition and must be filed within TWO MONTHS of the mailing date of this decision in order to be considered timely.

Should there be any questions with regard to this letter please contact Bruce Campell by letter addressed to the Director, Technology Center 1600, P.O. Box 1450, Alexandria, VA, 22313-1450, or by telephone at (571) 272-0974 or by facsimile transmission at (571) 273-0974.

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